ThermoFisher
SCIENTIFIC

510(k) SUMMARY

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K073191

FEB 28

A. Introduction:

According to the requirements of 21 CFR 807.92 the following information provides sufficent detail to understand the basis for a determination of substantial equivalence.

B. Submitter's information

Name:	Thermo Fisher Scientific Oy
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Contact person:	Päivi Sormunen, Vice President of QRC
Date of Preparation:	February 13th, 2008

C. Device name

Proprietary name:	Alkaline Phosphatase (IFCC) plus, codes 981832 and 981833
Common name:	Alkaline Phosphatase (IFCC)
Classification:	Clinical Chemistry
Class:	II
Product Code:	CJE
Proprietary name:	eCal, code 981830
Common Name:	Calibrator, Multi-Analyte Mixture
Classification:	Clinical Chemistry
Class:	II
Product Code:	JIX
Proprietary name:	Nortrol, code 981043
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY
Proprietary name:	Abtrol, code 981044
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY

D. Intended Use

Alkaline Phosphatase (IFCC)
For *in vitro* diagnostic use in the quantitative determination of alkaline phosphatase (orthophosphoric - monoester phospho-hydrolase, alkaline optimum, EC 3.1.3.1) activity in human serum or plasma on T60 instruments according to the IFCC method.

eCal
For *in vitro* diagnostic use on T60 instrument. eCal is used as a calibrator for enzyme tests using methods defined by Thermo Fisher Scientific Oy.

Nortrol
For *in vitro* diagnostic use for quantitative testing on T60 instrument. Nortrol is a control serum to monitor trueness and precision of the analytes listed in the separate Nortrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

Abtrol
For *in vitro* diagnostic use for quantitative testing on T60 instrument. Abtrol is a control serum to monitor trueness and precision of the analytes listed in the separate Abtrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

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E. Indications for use

The Alkaline Phosphatase test system is intended for quantitative *in-vitro* diagnostic determination of the activity of the enzyme Alkaline Phosphatase in serum and plasma on T60 instrument according to the IFCC method. Measurements of alkaline phosphatase are used in the diagnosis and treatment of liver and bone diseases.

For eCal Calibrator, Nortrol and Abtrol see intended use.

F. Substantial Equivalence

Bayer Corporation, model Bayer ADVIA 2400 Chemistry System.

Bayer Corporation item: Bayer ADVIA Alkaline Phosphatase (ALPAMP) assay.

G. Substantial equivalence -similarities

Alkaline Phosphatase (IFCC) Plus is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Bayer ADVIA Alkaline Phosphatase (ALPAMP) assay (K991576).

The following table compares the Alkaline Phosphatase with the predicate device.
Table 1

Attribute	**New device #1**	**Predicate device #1**
Intended Use	For *in vitro* diagnostic use in the quantitative determination of alkaline phosphatase (orthophosphoric - monoester phospho-hydrolase, alkaline optimum, EC 3.1.3.1) activity in human serum or plasma on T60 instruments according to the IFCC method (1).	For *in vitro* diagnostic use in the quantitative determination of alkaline phosphatase in human serum or plasma on the ADVIA Chemistry systems. Such measurements are used in the diagnosis and treatment of hepatobiliary and bone disease.
Indication for Use	The Alkaline Phosphatase test system is intended for quantitative *in-vitro* diagnostic determination of the activity of the enzyme Alkaline Phosphatase in serum and plasma on T60 instrument according to the IFCC method. Measurements of alkaline phosphatase are used in the diagnosis and treatment of liver and bone diseases.	See intended use.
Assay Protocol	ALP catalyzes the hydrolysis of p-nitrophenylphosphate. The formation of p-nitrophenol in alkaline solution is followed at 405 nm.	Alkaline phosphatase hydrolyzes *p*NPP substrate to form *p*-nitrophenol. The reaction is followed by the colorimetric measurement of the rate of formation of *p*-nitrophenol at 410/478 nm, which is proportional to the alkaline phosphatase activity.
Traceability/Standardization	The Alkaline Phosphatase (IFCC) Plus method is traceable to the molar absorbance coefficient of p-nitrophenol.	The ADVIA Alkaline Phosphatase (ALPAMP) method standardization is traceable to the IFCC reference method via patient sample correlation.
Sample Type	Serum, plasma (Li-heparin)	Serum, plasma (Li-heparin)
Reagent Storage	Reagents in unopened vials are stable at 2…8 °C until the expiration date printed on the	Unopened reagents are stable until the expiration date printed on the

Attribute	New device #1	Predicate device #1
	label when protected from light.	product label when stored at 2° – 8°C.
Expected Values	Male: 53 - 128 U/l (0.9 - 2.18 µkat/l) at 37 °C Female: 42 - 98 U/l (0.71 - 1.67 µkat/l) at 37 °C	45-129 U/L
Instrument	T60 and DPC T60i, DPC T60i Kusti	ADVIA® 2400 Chemistry system.
Measuring Range	20 – 1000 U/L	0-1100 U/L

Attribute	New device #1	Predicate device #1
Precision	**Within run** Level 91 U/l SD= 0.7 CV(%)= 0.7 Level 127 U/l SD= 0.9 CV(%)= 0.7 Level 374 U/l SD= 2.0 CV(%)= 0.5 Level 41 U/l SD= 0.5 CV(%)= 1.1 Level 810 U/l SD= 6.6 CV(%)= 0.8 **Between run** Level 91 U/l SD= 0.8 CV(%)= 0.9 Level 127 U/l SD= 1.1 CV(%)= 0.9 Level 374 U/l SD= 2.0 CV(%)= 0.5 Level 41 U/l SD= 1.4 CV(%)= 3.5 Level 810 U/l SD= 2.5 CV(%)= 0.3 **Total** Level 91 U/l SD= 2.9 CV(%)= 3.2 Level 127 U/l SD= 2.6 CV(%)= 2.0 Level 374 U/l SD= 8.4 CV(%)= 2.3 Level 41 U/l SD= 1.5 CV(%)= 3.7 Level 810 U/l SD= 18.5 CV(%)= 2.3	**Within run** Level 68 U/l SD= 0.9 CV(%)= 1.3 Level 148 U/l SD=2.1 CV(%)= 1.4 **Total** Level 68 U/l SD= 2.2 CV(%)= 3.2 Level 148 U/l SD= 3.8 CV(%)= 2.6

Attribute	New device #1	Predicate device #1
Method Comparison	y = 1.023x - 1.61 R = 0.998 range from 14 to 1752 U/l N = 154	Comparison with Advia 1650 (serum): y = 1.00x + 1.1 r = 0.998 n = 402 range: 26 to 693 U/l Comparison with reference method (serum): y = 1.04x – 14.6 r = 0.998 n = 96 range: 49 to 1050 U/l
Limitations	**Lipemia**: No interference found up to 1000 mg/dL (10 g/l) of Intralipid. **Hemolysate:** No interference found up to 300 mg/dl (3 g/l) of hemoglobin **Bilirubin, conjugated:** No interference found up to 58 mg/dL (1000 µmol/l) of conjugated bilirubin. **Bilirubin, unconjugated:** No interference found up to 21 mg/dl (360 µmol/l) of unconjugated bilirubin.	**Lipemia (from Intralipid)**: No significant interference found up to 500 mg/dl of Intralipid. **Hemolysate:** No significant interference found up to 500 mg/dl of hemoglobin. **Bilirubin:** No significant interference found up to 25 mg/dl.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 28 2008

Thermo Fisher Scientific Oy
c/o Ms. Päivi Sormunen
Vice President of Industrial Solutions & QRC
Clinical Diagnostics Finland
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Re: k073191
Trade Name: Alkaline Phosphatase (IFCC) Plus, Ecal, Nortrol, Abtrol
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system.
Regulatory Class: Class II
Product Codes: CJE, JIX, JIY
Dated: February 06, 2008
Received: February 06, 2008

Dear Ms. Sormunen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K073191

Device Name: Alkaline Phosphatase (IFCC) Plus, eCal, Nortrol, Abtrol

Indication For Use:

The Alkaline Phosphatase test system is intended for quantitative *in-vitro* diagnostic determination of the activity of the enzyme Alkaline Phosphatase in serum and plasma on T60 instrument according to the IFCC method.
Measurements of alkaline phosphatase are used in the diagnosis and treatment of liver and bone diseases

For *in vitro* diagnostic use on T60 instrument. eCal is used as a calibrator for enzyme tests using methods defined by Thermo Fisher Scientific Oy

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For *in vitro* diagnostic use for quantitative testing on T60 instrument. Abtrol is a control serum to monitor trueness and precision of the analytes listed in the separate Abtrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073191